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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,807	01/22/2004	Stuart D. Shanler	132957.00101	4999

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EXAMINER	
CARTER, KENDRA D	
ART UNIT	**PAPER NUMBER**
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,807	SHANLER ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 13-16* is/are pending in the application.

4a) Of the above claim(s) *4-6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of December 4, 2008 made to the office action filed September 4, 2008. Claims 1-6 and 13-16 are pending. Claims 1 and 14-16 are amended and claims 4-6 are withdrawn based on Applicant's election of oxymetazoline as the adrenoreceptor agonist in the reply filed June 20, 2007. Claims 7-12 and 17-24 are canceled.

The Examiner would like to note that the claim identifiers for claims 4 to 6 are incorrect. The current claim identifier states"(original)", which should be "(withdrawn)".

The Applicant's arguments of Leal in the the following rejections were found persuasive, thus the rejection is withdrawn 1) the 35 USC 102(b) rejection of claims 1-3, 14 and 16 as being anticipated by Leal as evidenced by Yu et al.; and 2) the 35 USC 103(a) rejection of claims 13 and 15 as being unpatentable over Leal in view of Yu et al.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 USC 103(a) rejection of claims 1-3 and 13-16 as being unpatentable over Yu. et al. in view of Applicant's admitted prior art were found not persuasive, thus the rejection is upheld.

Due to the Applicant's arguments of Yu et al. not being persuasive, the previous rejection is repeated below. The Applicant's arguments in regards to Yu et al. are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu. et al. (US 2004/0220259 A1) in view of Applicant's admitted prior art (see specification, page 1, background of the invention, paragraphs 1 and 2; page 7, lines 16 and 17).

Yu et al. teach a method of topically treating dermatological disorders associated with dilated blood vessels, such as rosacea (see claims 1 and 4; page 1, paragraph 5, last 2 lines and paragraph 11, lines 1 and 12; addresses claim 1) comprising a topical agent such as oxymetazoline (see claims 2 and 26, line 22; addresses claims 1-3). Other ingredients may be incorporated in the compositions as long as the therapeutic

properties of the polyhdroxy acids or lactones are not impeded, and in most cases, inclusion of more than one agent is desirable. Agents include anti-acne, anti-bacterial, anti-inflammatory, anti-histamine, anti-pruriginous, anesthetic, anti-viral, sunblock, sunscreen, and skin lightening agents (see page 4, paragraph 44, last 5 lines; paragraph 45 in its entirety; addresses claim 13). The composition can be formulated into gels, creams, lotions, solutions, sprays, emulsions, bars, shampoo(i.e. soaps), or those well known in the art (see page 3, paragraph 37; addresses claims 14 and 15).

Yu et al. does not specifically teach a composition comprising oxymetazoline to treat rosacea, or wherein rosacea is elicited by the factors disclosed in claim 16.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and oxymetazoline to treat rosacea because the disorders treated by Yu et al. include rosacea because it is a condition associated with dilated blood vessels (see claims 1 and 4; page 1, paragraph 5, last 2 lines and paragraph 11, lines 1 and 12). Additionally oxymetazoline is a known vasoconstrictor (see specification page 7, lines 16 and 17), thus one would be motivated to use a vasoconstrictor in the composition of Yu et al. to reduce the dilated blood vessels that arise in rosacea.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Yu et al. and wherein rosacea is

elicited by the factors disclosed in claim 16 because it is known in the art that rosacea is elicited by the factors disclosed in claim 16 (see specification, page 1, paragraph 3), and then dilation of the facial blood vessels occur (see specification, page 1, paragraph 1, lines 1-2). Therefore, regardless of how rosacea is elicited the method of Yu et al. still treats the rosacea itself by reducing the blood vessel dilation.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive in regards to Yu et al.

> The Applicant argues that Yu is not prior art because the priority document (the provisional Application No. 60/460,322) fails to disclose a method for treating rosacea by topically administering to the skin a therapeutically effective amount of at least one α_1 adrenoreceptor agonist as recited in the pending claims. The '322 Provisional application only Provides evidence that the topical administration of a polyhydroxy-lactone was effective in reducing the erythema. The '322 Provisional Application is silent as to an effective amount of oxymetazoline to treat rosacea or whether it is even effective to treat rosacea or erythma at all. It is merely listed as an additional agent that could be incorporated into the polyhydroxy-lactone composition among myriad other agents. Additionally, it is respectfully submitted that in order for a reference to be considered prior art it must be enabling. The '322 Provisional fails to disclose any link between oxymetaxoline and rosacea and undue experimentation would be required to establish such a link.

The Examiner disagrees because the Provisional Application teaches the following: 1) compositions comprising polyhydroxy-lactones for the topical treatment of reactive blood vessels which include conditions such as rosacea (see page 1,lines 4-5, 16-17,

24, and 30); and 2) examples of cosmetic, pharmaceutical and other topical agents that can be added include oxymetazoline (see page 4, line 30 and page 5, line 24.) The publication, claims the treatment of rosacea and the use of oxymetazoline (see claims 4 and 26). Thus, the treatment of rosacea is enabled because it is a condition that results from reactive blood vessels, and the Provisional successfully demonstrates the treatment of a condition that results from reactive blood vessels. An example is not required for each and every species. The motivation to treat rosacea with the specific additional active agent oxymetazoline is because oxymetazoline is a known vasoconstrictor (see specification page 7, lines 16 and 17), thus one would be motivated to use a vasoconstrictor in the composition of Yu et al. to reduce the dilated blood vessels that arise in rosacea. Thus, the link between oxymetaxoline and rosacea is that oxymetazoline is a vasoconstrictor and rosacea is a condition that is associated with dilated blood vessels. In KSR, the Supreme Court rejected the rigid application of the teaching, suggestion, and motivation test by the Federal Circuit, stating that "The principles underlying [earlier] cases are instructive when the question is whether a patent claiming the combination of elements of prior art is obvious. When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." KSRInt'I v. Teleflexlnc., 127 S. Ct. 1727, 1740 (2007). Applying the KSR standard of obviousness to the findings of fact, it would have been obvious to apply the method of the Yu et al.

reference and oxymetazoline in order to constrict the blood vessels or rosacea, which is a condition that is associated with dilated blood vessels.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617